K002958

I. 510 (K) SUMMARY

DEC 1 9 2001

Submitted By:
Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular Incorporated
P.O. Box 529
Leechburg, PA 15656
(724) 845-8621
September 21, 2000

Device:

Trade Name:	Cook Vascular Shapeable Doppler Flow Probe
Common/Usual Name:	Blood Flow Sensor or Probe, Doppler Catheter
Proposed Classification Name:	Diagnostic Ultrasonic Transducer probe, 21 CFR Part 892.1580 (90-ITX)

Predicate Devices:
The Cook Vascular Shapeable Doppler Flow Probe is substantially equivalent to the currently marketed COOK-Swartz Doppler Flow Probe D.C. #K964001, with respect to intended use, material composition, and method of operation.

Device Description:
The Cook Vascular Shapeable Doppler Flow Probe is intended for monitoring blood flow through vessels in patients intraoperatively and during intraoperative neuro-vascular procedures. The Shapeable Doppler Flow Probe is supplied sterile, and non-pyrogenic and is intended for one-time use. Reasonable assurance of biocompatibility of the body fluid/tissue contacting materials comprising the device is provided by their established history of use in medical product manufacturing.

Substantial Equivalence:
The device will be manufactured according to specified process controls and a Quality Assurance Program, undergoing packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Vascular Incorporated. This device is similar with respect to indications for use, materials and physical construction to predicate devices in terms of section 510 (k) substantial equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2001

Thomas J. Kardos
Vice President, Regulatory Affairs
Cook Vascular, Inc.
P.O. Box 529
Route 66 River Road
LEECHBURG PA 15656-0529

Re: K002958
Trade Name: Cook Vascular Shapeable Doppler Flow Probe
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasound transducer
Regulatory Class: II
Product Code: 90 ITX
Dated: November 12, 2001
Received: November 13, 2001

Dear Mr. Kardos:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Cook Vascular Blood Flow Monitor, as described in your premarket notification:

Transducer Model Number

20 MHz Cook Vascular Shapeable Doppler Flow Probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

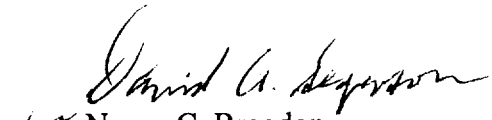
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K002958

Appendix F

Diagnostic Ultrasound Indications for Use Form

Cook Vascular Shapeable Doppler Flow Probe

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				N						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The Cook Vascular Shapeable Doppler Flow Probe is intended for use with the Cook Vascular Blood Flow Monitor, for monitoring blood flow in vessels intraoperatively and during intraoperative neuro-vascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hegarty

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K002958

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Cook Vascular Blood Flow Monitor (D.C. #K964001)

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)				P						
Intraoperative Neurological				N						
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)				P						

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: The Cook Vascular Blood Flow Monitor is used with the COOK-Swartz Doppler Flow Probe (D.C. #K964001) and the Cook Vascular Shapeable Doppler Flow Probe to monitor blood flow intraoperatively, during intraoperative neuro-vascular procedures, and following reconstructive microvascular procedures, re-implantation and free flap transfe

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lilyquist

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K962958

Prescription Use (Per 21 CFR 801.109)